

REMARKS

The applicants appreciate the Examiner's thorough examination of the application and request reexamination and reconsideration of the application in view of the preceding amendments and the following remarks.

The Examiner rejects claims 1-14 under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, stating that the recitation in claim 1, lines 3-4 is indefinite, and requests clarification and/or correction. Claim 1 has been amended in response.

The Examiner also rejects claims 1 and 4-14 under 35 U.S.C. §102(b) as being anticipated by *Willner et al.* WO 98/40739.

The applicants' amended claim 1 recites a smart culture vessel for holding a sample to be tested in a culture medium comprising a bio-sensor sealed in the vessel in the culture medium with the sample. The bio-sensor has a coating for attracting at least one pathogen expected in the sample, and a detection circuit responsive to the bio-sensor for indicating the presence of a pathogen on the bio-sensor.

Numerous disadvantages are overcome by the applicant's claimed invention with the bio-sensor sealed in the vessel. The applicant's claimed invention continuously monitors and instantly detects a pathogen in a culture medium, without the need to draw samples for testing. There is no need to remove the bio-sensor, to add solutions to the vessel during monitoring, or to contact the bio-sensor to other agents. Additionally, the sealed system decreases the chance of contamination of the sample to be tested, or contamination of the outside environment by the sample contents, resulting in greater accuracy and increased safety.

In contrast, *Willner et al.* does not disclose a sealed vessel or the advantages of the

applicant's claimed invention. In order to accomplish the results intended, *Willner et al.* discloses that after contact with the specimen the sensing member ("bio-sensor") is contacted with sensitivity increasing agents. See *Willner et al.* page 12, lines 1-10. Alternatively, where the concentration of more than one type of cell is sought, the specimen is first contacted with the sensing member, then the sensing member is contacted with a first cell-specific agent. Thereafter, to verify the existence of a second type of cell, a second cell-specific binding agent is then contacted with the sensing member. See *Willner et al.* page 12, lines 11-27. *Willner et al.* is thus in stark contrast to the applicant's claimed invention, where monitoring of the sample is done continuously, with resultant instantaneous detection of various pathogens, in a self-contained sealed vessel without the need to withdraw samples (or the bio-sensor), introduce agents or expose the bio-sensor to additional agents and consequently run the risk of contamination of or by the atmosphere or such agents. See, e.g., the specification at page 4, lines 7-10 and page 8, line 18 through page 9, line 1.

The applicant further notes that the secondary cited reference European Pat. No. EP0215669 to *Karube et al.* discloses a flow cell into which various fluids are drawn including liquid, blood samples, phosphate buffers, and/or removal agents. See, e.g., the *Karube et al.* Abstract and page 4, line 64 through page 5, line 20. Again, the disclosed flow cell is not sealed and includes the inherent possibility of contamination. Also, more time is required to complete the operation. Particularly, the introduction of various agents increases the risk of contamination by such outside agents or environment, and the *Karube et al.* process of introduction of various agents does not equate to continuous monitoring.

In summary, the applicant's independent claim 1 is not anticipated by *Willner et al.* since *Willner et al.* clearly fails to disclose each and every element of the applicant's claim 1.

Accordingly, claim 1 is in condition for allowance. Claims 2-14 depend directly or indirectly from claim 1 claimed by the applicant and thus are also in condition for allowance.

The Examiner further rejects claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over *Willner et al.* in view of European Pat. No. EP0215669 to *Karube et al.* As noted above, claims 2 and 3 depend directly or indirectly from claim 1, and thus are allowable for at least that reason, as well as the other reasons set forth herein.

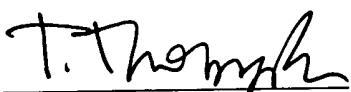
#### CONCLUSION

Accordingly, claims 1-14 are in condition for allowance.

Each of Examiner's have been addressed or traversed. Early and favorable action is respectfully requested.

If for any reason this Response is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the undersigned or his associates, collect in Waltham, Massachusetts at (781) 890-5678.

Respectfully submitted,

  
\_\_\_\_\_  
Thomas E. Thompkins, Jr.  
Reg. No. 47,136